

GUIDANT

November 29, 1999

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Dockets Management Branch,
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers lane, Room 1061 (HFA-305)
Rockville, MD 20852

RE: Docket No. **99D-2873**
Comments on Evidence Models for the Least Burdensome Means to Market Draft
Guidance

Dear Sir/Madam:

On behalf of Guidant Corporation, Vascular Intervention Group, provided below are comments regarding the Guidance for Industry and FDA Reviewers on Evidence Models for the Least Burdensome Means to Market.

Guidant Corporation, Vascular Intervention Group, is in general agreement with the comments provided by the Health Industry Manufacturers Association (**HIMA**) and with the comments provided by Guidant Corporation, Cardiac Rhythm Management division.

Furthermore, Guidant Corporation, Vascular Intervention Group, would like to add the following comments:

General principles

The second principle listed advises FDA reviewers and sponsors to apply guidance documents and standards of identity consistently, and identify the types of data that constitute **valid scientific** evidence. Sponsors would gladly apply guidance documents and standards in support of product submissions. The responsibility to ensure consistent application across all product submissions remains with the FDA. In addition there must be consistent interpretation of guidance documents and standards within the branches of FDA.

As listed in the fifth principle it is important that FDA and sponsors maintain open communication, especially with respect to determining the least burdensome means for evaluating specific medical device submissions. A guidance document, such as this one, will be the basis for that decision-making process.

99D-2873

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FDA Model

Guidant Corporation, Vascular Intervention Group, disagrees with the approach described in this section. Under Question #2, we do not believe that the alternative question that can be asked regarding randomized controlled trials (RCT) is appropriate. Although it could be true that an RCT is the least burdensome means to provide reasonable assurance of safety and effectiveness for certain devices, this is not the appropriate starting point for a discussion of this type. It is very important that a guidance document describing the process for obtaining the least burdensome means of obtaining safety and effectiveness information does not have the “most” burdensome method as a starting point. Although it could be argued that the lowest level of burden cannot be used to arrive at a least burdensome approach, this certainly must be considered.

An alternative is to begin a discussion of a least burdensome approach with the “Points to Consider” listed under each “Question” of the draft guidance. A flowchart could be developed using these points as criteria, which could then form the framework for justification of the clinical data requirement.

In summary, Guidant Corporation, Vascular Intervention Group, would like to reiterate that it is very important to continue open communication with the agency and appreciates the opportunity to provide comments. It is also important to establish an appropriate starting point for a discussion on the least burdensome means of obtaining safety and effectiveness information.

Respectfully,

Grant D. Benson on behalf of

Guidant Corporation
Vascular Intervention Group

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